



Scancell Holdings plc

("Scancell" or the "Company")

Phase 2 SCOPE trial of SCIB1 vaccine in metastatic melanoma patients expanded

Additional cohort to test SCIB1 vaccine in combination with checkpoint doublet therapy

Protocol amendment broadens patient population for inclusion in the trial and enables faster recruitment to remain on track to deliver initial efficacy data in 2022

SCIB1 to be delivered using PharmaJet Needle-free Injection System

Scancell Holdings plc (AIM: SCLP), the developer of novel immunotherapies for the treatment of cancer and infectious disease, today announces an update to the Phase 2 SCOPE clinical trial being conducted at multiple centres in the UK. Following the approval of a protocol amendment by the Medicines and HealthCare products Regulatory Agency (MHRA), the trial will include a cohort of melanoma patients who will receive SCIB1 plus doublet therapy consisting of ipilimumab (Yervoy®) plus nivolumab (Opdivo®) in addition to the cohort who will receive SCIB1 with pembrolizumab (Keytruda®). The updated protocol also allows all patients to receive the SCIB1 vaccine as a needle-free injection.

SCIB1 is the lead product from the Company's ImmunoBody® immunotherapy platform, which uses the body's immune system to identify, attack and destroy tumours. In a Phase 1/2 clinical trial, 14 out of 16 resected patients (89%) survived for more than 5 years following vaccination with SCIB1. The original Phase 2 study was designed to assess whether the addition of SCIB1 treatment to pembrolizumab results in an improvement in patient outcomes for patients with metastatic disease. The primary objectives of the trial are tumour response rate, progression-free survival and overall survival in patients with advanced melanoma. The amendment to the SCOPE protocol follows changes in the treatment landscape where the current most common treatment for metastatic melanoma patients is a doublet therapy combining two checkpoint inhibitors, ipilimumab and nivolumab.

Under the updated protocol the company will also test the SCIB1 vaccine delivered via needle free injection. To date, SCIB1 has been delivered using electroporation to enhance the uptake and presentation of the DNA vaccine to the immune system and, although electroporation is a proven delivery method, the Company believes that needle-free injection could provide enhanced patient acceptance. The Company is currently using PharmaJet Needle-Free Injector Systems in its COVIDITY trial being carried out in South Africa.

Professor Lindy Durrant, Chief Executive Officer, Scancell, commented: "The approved amendments will expand the patient population eligible to receive SCIB1 and are therefore expected to increase recruitment rates, allowing the study to remain on track to deliver initial efficacy data in 2022. We believe that SCIB1 administration in combination with doublet therapy has the potential to offer greater efficacy than checkpoint inhibitors alone, without increasing toxicity."

Professor Poulam Patel, Chief Investigator, commented: "The treatment landscape for metastatic melanoma patients has changed and most patients in the UK are now treated with ipilimumab/nivolumab doublet therapy. As the Chief Investigator for this combination study, I am delighted to be working with Scancell to determine if the addition of SCIB1 to doublet therapy improves response rates. In addition, the delivery of SCIB1 via a needle-free injection will be welcomed by our healthcare team administering the vaccine."

Chris Cappello, President and CEO, PharmaJet, commented: "We are pleased to be partnering with Scancell as they expand their Phase 2 trial with a needle-free delivery option for patients with advanced melanoma. In addition to increasing patient acceptance, our partners have published results showing superior results to other vaccine delivery systems."

Further information relating to the Company's clinical trials can be found on www.scancell.co.uk and at https://clinicaltrials.gov.

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014 (MAR).



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About Scancell

Scancell is a clinical stage biopharmaceutical company that is leveraging its proprietary research, built up over many years of studying the human adaptive immune system, to generate novel medicines to treat significant unmet needs in cancer and infectious disease. The Company is building a pipeline of innovative products by utilising its four technology platforms: Moditope[®] and ImmunoBody[®] for vaccines and GlyMab[®] and AvidiMab[®] for antibodies.

Adaptive immune responses include antibodies and T cells (CD4 and CD8), both of which can recognise damaged or infected cells. In order to destroy such cancerous or infected cells, Scancell uses either vaccines to induce immune responses or monoclonal antibodies (mAbs) to redirect immune cells or drugs. The Company's unique approach is that its innovative products target modifications of proteins and lipids. For the vaccines (Moditope[®] and ImmunoBody[®]) this includes citrullination and homocitrullination of proteins, whereas its mAb portfolio targets glycans or sugars that are added onto proteins and / or lipids (GlyMab[®]) or enhances the potency of antibodies and their ability to directly kill tumour cells (AvidiMab[®]).

For further information about Scancell, please visit: https://www.scancell.co.uk/